

March 17, 2023

VIA ECF FILING ONLY

Hon. Lorna G. Schofield, U.S.D.J.
United States District Court, SDNY
500 Pearl Street
New York, NY 10007

Re: *Powers v. Memorial*; Docket No. 1:20-cv-02625; Plaintiff's Response to Defendants' Objections to the First Set of Plaintiff's Demonstratives.

Dear Judge Schofield:

Plaintiff offer the following response to Defendants' objections to the first set of Plaintiff's demonstratives. (Doc. 426).

PD-1

This is a physical model of an anatomically correct liver that Plaintiff will make available for inspection prior to trial. Defendants reserve their right to object.

PD-4

This Court has previously overruled Defendants' objections to Plaintiff's use of 1-10 scale to rank medical related judgment and medical care on a numerical basis. This demonstrative is a visual representation to summarize that testimony. This Court found that these numbers "are analogous to using adjectives and adverbs (like "poor" and "extremely poor") to express his opinion and are more anodyne and less inflammatory than many other descriptors." (Doc. 409). Defendants are simply renewing their previously denied motion in limine.

PD-6

The radiological image is correct. There was a PET scan taken on 3/21/2017 that Defendants produced in discovery. Plaintiff has confirmed that this image is numbered in Plaintiff's radiology viewer as Series 601. It is unknown why Defendants see a different series and whether the use of a different radiology viewer changes the numbering, but this image is accurately identified. Plaintiff is using the FDA cleared software OsiriX MD to view, copy, and identify all images.

PD-7

The material objected to by Defendants on page 1 are portions of the Ethicon probe manual admitted in evidence by this Court overruling Defendants' motion in limine. (Doc. 409). As the

parties described in argument at the final pretrial conference, it is the regular practice of ablation manufacturers to test, publish guidelines, and market their product using bovine livers. Plaintiff does not intend to imply to the jury that these manual excerpts are anything other than the guidelines from bovine livers and have agreed to make that clearer on this demonstrative and re-submit.

Defendants object to Pages 3–10 asserting that Plaintiff manipulated these images. That is wrong.

Radiology such as CT and PET is unique because each study or exam is not just one image, but multiple series of images that can be in the hundreds or thousands. Each series of images has one or up to hundreds of images viewable from the front (coronal), side (sagittal), or bottom (axial). These images are thin (5mm) slices of a body, like an ultra-thin slice from a loaf of bread, that one can scroll through to view three-dimensional images. Any professional radiological software has the ability to view multiple slices (a series) at once by selecting the Maximum Intensity Projection (MIP) viewer, which stacks the slices of the body on top of each other, so you can view the images through each other for 3D view of the anatomy but still from the original view (such as axial). Radiological software also has the ability to view a series selecting the 3D MIP viewer, which stacks the slices of the body on top of each other in a way so you can view the images through each other for a 3D view of the anatomy that can be rotated (so an axial series can be viewed from the front). It does not alter, manipulate, or in any way change the images.

These images are the raw, *unmanipulated* radiological images produced by Defendants as seen in radiology viewer OsiriX MD which is cleared by the FDA as a Class II Medical Device for diagnostic imaging in medicine. As labeled on the image, this is the “MIP stack 39 of 39 images.” These images were taken during the ablation procedure at issue. Plaintiff’s expert will use them to walk the jury through the procedure, step-by-step, to support his opinions that the performance of the procedure violated the standard of care. They will assist the jury in understanding the procedure, why deciding to proceed with the procedure was poor judgment, and the damage caused during the procedure. This is all necessary for Plaintiff to meet his burden. Plaintiff’s experts participated in and approved the creation of these images and will testify that they are true and accurate copies of the raw radiological images.

PD-8

Defendants note that page 2 has a typographical error, that it is slide 27, not 29. Plaintiff has fixed this error and will re-submit this demonstrative.

Defendants claim that the dates on pages 20 and 34 are wrong. Plaintiff’s counsel checked on these and they are the correct date. On page 20, the drains seen were placed on 4/14/2017. The imaging from 4/21/2017 is merely the best radiological view of the earlier-placed drains. Plaintiff’s expert will explain and elaborate on this as they describe the post-ablation outcome and procedures, however, Plaintiff will amend the date to avoid confusion.

Likewise, on page 34, the 7/27/2017 CT represents a clear view of the drains, pump catheter, and embolization coil placed on recent prior dates. Plaintiff's expert will explain what they show to help the jury understand the consequences of the damage Erika sustained as a result of the procedure; however, to appease defendants and avoid the risk of confusion they have expressed, Plaintiff will remove the date on this slide.

Finally, Defendant's objection that the embolization of July 4, 2017, resulted from the injuries sustained during the ablation procedure lacks any support by their experts and has the support of Plaintiff's expert. Dr. DeMatteo opines that the ablation resulted in an injury to the hepatic artery that necessitated the embolization on July 4, 2017. In discussing the post-ablation injuries, Dr. Ronald DeMatteo states:

The bile duct and the portal vein were damaged. Regarding the hepatic artery, there was a possible hepatic artery pseudoaneurysm (as written in the radiologist's peri-procedure note) on the arteriogram performed in April for bleeding. In July at OHSU, the hepatic artery was found to be occluded beyond the site of active bleeding, which was diagnosed with an arteriogram and treated with embolization.

Dr. Ronald DeMatteo's report at page 11–12, attached as Exhibit A. The medicine behind this opinion, which Dr. DeMatteo will explain at trial, is that a hepatic arterial pseudoaneurysm (HAPs) is a consequence of trauma to the hepatic artery. This HAP weakens the artery which can rupture weeks to months after the trauma, causing severe acute abdominal bleeding requiring emergency coil embolization. *See Exhibit B Subhendu Mohanty, Emergency hepatic artery embolization in a patient with post-traumatic ruptured hepatic artery pseudoaneurysm, 7:3 J. EMERGENCY, TRAUMA & SHOCK 246, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4126131/>* In his opinion, Dr. DeMatteo makes clear that the ablation resulted in a HAP that led to the acute bleeding event on July 4, 2017 from rupture in July which Dr. John Kaufman of OHSU embolized in an emergency procedure on July 4.

Dr. DeMatteo also testifies to this in his deposition, stating that it was “a very high likelihood” that the hepatic artery rupture and hemorrhage that Dr. Kaufman embolized on July 4, 2017 was caused by the damage the hepatic artery suffered during the ablation. *See Exhibit C Dr. DeMatteo's deposition at 123:12–24.*

Medical Illustrations

Defendants then object that each of Plaintiff's medical illustrations contained in PD-8, PD-9, PD-10, PD-13, and PD-21 are inflammatory and misleading hybrid illustrations. Plaintiff has a number of illustrations that are colorized accurate pictures of Erika Zak's own radiology. Plaintiff's Demonstrative PD-12 contains a set of reconstruction documents that chronical the process for tracing, colorizing, and viewing Erika Zak's own films. Plaintiff's experts participated in and approved the creation of these colorized images and will testify that they are true and accurate copies of the raw radiological images.

This will assist the court and the jury in several ways. Radiological images are technical and complex. Viewing and understanding radiology is a skill that requires medical training and is often difficult for a layperson to understand. A colorized medical illustration simplifies and clarifies the images by colorizing the radiology in a way that a non-medical professional can see and understand. The jury will be able to better visualize the anatomy, procedures, and injuries in an accurate colorized image of Erika Zak's own imaging.

PD-9

In addition to objecting to the medical illustrations addressed above, Defendants object to the depictions of biliary drains as cumulative. Apart from two chest views, showing distinct parts of Erika's chest from 2/5/2018 (pages 11 and 12), these are each from different scans on different dates. Erika Zak had dozens of procedures during her over 100 days in the hospital *after* the ablation. These scans represent only a small selection. Defendants attempt to limit Plaintiff on how much of the injury at issue he may present is an undue limit on Plaintiff's burden of proof. The injury to her bile ducts is one of the primary results of the ablation that led to Erika's liver failure.

PD-10

Plaintiff addresses Defendants' objections to the medical illustrations above.

PD-11

Defendants re-lodge their objections this Court denied in its ruling on their motion in limine No. 1. (Doc. 409). As this Court concluded, the evidence is "highly probative and is not confusing or unfairly prejudicial." Dr. Navuluri is Plaintiff's expert interventional radiologist. He is an expert at understanding time and wattage as applied in a microwave ablation. He need not know the details of how the machine downloads the data to understand the clearly-outlined time and wattage data recorded by the microwave ablation machine at issue. Defendants are re-lodging their authenticity objection. Plaintiff proved up the authenticity of the data by declaration and this Court admitted that evidence in denying Defendants motion in limine. (Doc. 409).

Dr. Navuluri has applied his expertise to the time and wattage data produced by Ethicon to form his opinions. This demonstrative is an empty chart to simplify that time and wattage data for the jury's understanding. Dr. Navuluri will fill in the chart during his testimony for the jury to explain the time and wattage used in this procedure as captured by the Ethicon NeuWave Ablation Machine software. If Defendants take further issue with the reliability of Dr. Navuluri's opinions or the data from Ethicon, they may address that through cross examination.

PD-12

As described above in response to Defendants objections to Plaintiff's medical illustrations, this is a set of documents detailing how Plaintiff's traced, viewed in three-dimensions, and colorized

Erika Zak's own radiology. Plaintiff, again, did this in the radiology viewer OsiriX MD which is cleared by the FDA as a Class II Medical Device for diagnostic imaging in medicine. Plaintiff's experts participated in and approved the creation of these images and will testify that they are true and accurate copies of the raw radiological images.

PD-13

In addition to objecting to the medical illustrations as addressed above, Defendants object to the National Comprehensive Cancer Network ("NCCN") guidelines and claim they are misinterpreted. Both Plaintiff and Defendants include the NCCN Guidelines from March 13, 2017, that Dr. Sofocleous agreed establish the standard of care on their respective exhibit lists. *See* P-187; D-25. Defendants claim that SBRT is not listed on the same level as ablation and "the NCCN guidelines did not recommend radiation (ABRT) as standard of care." (Doc. 426). This is false.

The NCCN guidelines for colon cancer provide the following "Principles of the Management of Metastatic Disease" as the standard of care:

"The standard of care for patients with resectable metastatic disease is surgical resection. If resection is not feasible, image-guided ablation *or stereotactic body radiation therapy (SBRT; also called stereotactic ablative therapy [SABR]) are reasonable options*, as discussed in subsequent paragraphs."

NCCN guidelines attached as Exhibit D (emphasis added). The NCCN then lists the standard of care therapies, including "Liver or Lung Radiation": "The possible techniques include three-dimensional conformal radiation therapy (CRT), **SBRT**, and IMPRT." *Id.* (emphasis added). Tumor ablation is listed as another option further down the same list, which appears to be in alphabetical order. *Id.*

Contrary to Defendants' claim, SBRT is not only listed as standard of care, is the NCCN Guidelines consider it on the same level as ablation, both equal secondary options to surgical resection.

Plaintiff did not include of immunotherapy to argue that the MSK doctors failed to consider it at that time; Plaintiff intended to use it with Plaintiff's expert to explain the appropriateness of Erika Zak' eventual prescription of immunotherapy by OHSU. However, Plaintiff has agreed to remove it from this demonstrative.

PD-21

Plaintiff has addressed Defendants' objections to the medical illustrations above.

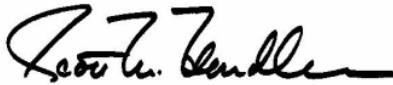
PD-22



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Defendants argued in their Motion in Limine No. 8 to preclude testimony or argument that Ms. Zak has been “cured” of cancer. (Doc. 303). In response, Plaintiff made clear that he would not make any argument that Erika was “cured” of cancer but intended to argue (as expert testimony and the medical record supports) that as of February 2018 she was cancer free, after four months of treatment with Pembro and remained cancer free for the last 20 months of her life. Thus, this Court denied Defendants’ motion as moot. (Doc. 409). Plaintiff outlined the support for Erika Zak being “cancer free” in response to the prior motion in limine and respectfully refers the Court to that memorandum (Doc. 353) if further argument is needed.

Respectfully submitted,
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